DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Mint Medical GmbH
% Mr. Matthew Stevens
Counsel
135 Montgomery Street, Suite 18J
JERSEY CITY NJ 07302

Re: K142647
Trade/Device Name: mint Lesion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 9, 2015
Received: March 9, 2015

Dear Mr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number
K142647

Device Name
mint Lesion

Indications for Use
Mint Lesion is a software solution intended to be used for viewing, manipulation, communication, storage, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. Mint Lesion is a software only medical device which will be delivered on CDROM / DVD to be installed by trained service personnel.

Mint Lesion is a medical diagnostic application for viewing, manipulation, 3D visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MPR, MIP and volume rendering.

Mint Lesion enables visualization of information that would otherwise have to be visually compared disjointedly. Mint Lesion provides analytical tools to help the user assess, and document the stage of a disease and/or the response to therapy in accordance with user selected standards. Mint Lesion supports the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Oncology, and Nuclear Medicine environments.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. Mint Lesion is a complement to these standard procedures. Mint Lesion is not to be used in mammography.

Type of Use

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 510(k) Summary

Identification of the Submitter

Submitter:	Dr. Jochen Neuhaus, Regulatory Affairs Manager Mint Medical GmbH Friedrich-Ebert-Str. 2 69221 Dossenheim / Heidelberg Baden-Württemberg Germany
Submitter's Phone:	(+49) 622-164-797-60
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Name / Address of Manufacturer:	Mint Medical GmbH Friedrich-Ebert-Str. 2 69221 Dossenheim / Heidelberg Baden-Württemberg Germany
Date of Submission:	12th of September 2014

Identification of the product

Proprietary Name:	mint Lesion
Common Name:	Image Processing Software
Classification:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
OncoTrac (Primary Predicative Device)	Mint Medical GmbH Germany	K111642 (Nov 18, 2011)
Syngo.via MI Workflows	Siemens Medical Solutions USA, Inc	K133644 (Feb 25, 2014)

Device Description

mint Lesion™ is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and visualization of medical image data. It runs on either a native or a virtualized Microsoft Windows platform.

mint Lesion™ functionality provides for communication, storage, processing, rendering, and display of DICOM compliant image data derived from various sources including anatomical datasets (e.g. CT, MRI) and functional datasets (e.g. PET), lesion measurement, tabulation and summation of measurements, lesion categorization and standard evaluation in accordance with radiological staging and response criteria, and generation of a structured report. The user controls these functions with a system of interactive menus and tools.

The mint Lesion™ software has been extensively tested on Windows 64 bit systems by members of the development and quality control teams. A hazard analysis has been conducted and the level of concern has been classified as moderate. The release version of the software passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance.

Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk Management has been ensured via risk analysis in compliance with ISO 14971:2012 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Mint Medical GmbH adheres to recognized and established industry standards for development including ISO 13485 and IEC 62304.

Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed and that all hazard mitigations have been fully implemented.

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Substantial Equivalence Comparisons to Predicate Devices

The mint Lesion extended functionalities addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Manufacturer	Predicate Device Name	FDA Clearance Number
Mint Medical, Germany	OncoTrac	K111642
Siemens Medical Solutions USA, Inc	Syngo.via MI Workflows	K133644

The added capabilities to mint Lesion described in this 510(k) has similar functionalities that can be found in the predicate devices listed above. In comparison to the primary predicate device, the indications for use have been updated to include nuclear imaging modalities and to clarify and limit the scope of application to the purpose of assessment, staging and

documentation of a disease and/or the response to therapy. No change of technology was required to support the new imaging modalities. The additional predicate devices support all imaging modalities that mint Lesion supports. No new use was introduced by the change in the indications for use statement compared to the primary predicate device.

In summary, Mint Medical GmbH is of the opinion that mint Lesion does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

Conclusion

There are no differences in the Fundamental Technological Characteristics of the mint Lesion software as compared to the currently commercially available software listed above. Additionally, there have been no changes that raise any new issues of safety and effectiveness as compared to the predicate device. Based on this information, as well as the documentation in support of the modifications, it is Mint Medicals opinion that the mint Lesion software with the modifications outlined in this application is substantially equivalent to the predicate device.